K102683

JAN 6 2011

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	OB the-addition, LLC
TRADE NAME:	The-Addition
COMMON NAME:	Media, Coupling, Ultrasound
CLASSIFICATION NAME:	Diagnostic ultrasonic transducer, 21 CFR, 892.1570
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	MUI
PREDICATE DEVICES:	ScanTec Pad K031894 Embrace Gel Pad K072515

Substantially Equivalent To:
The-Addition is substantially equivalent in intended use, principal of operation and technological characteristics to the identified predicates.

Description of the Device Subject to Premarket Notification:

The-Addition is a pad that is temporarily applied to the ultrasound transducer and the toco transducer to facilitate patient comfort and aid in the retention of ultrasonic coupling gel.

The-Addition is provided non-sterile for single use and is disposable.

Indication for Use:

The-Addition provides padding for patient comfort and aids in the retention of coupling media in a defined position.

Technical Characteristics:

The-Addition has similar physical and technical characteristics to the predicate devices. The-Addition and the identified predicates all provide for the retention of coupling media in a defined position.

Performance Data:

All necessary verification and validation testing has been performed for The-Addition to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, The-Addition is determined by OB the-addition, LLC, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 6 2011

Ms. Rebecca Pine
Consultant
OB the-addition, LLC
2206 Modoc Road #3
SANTA BARBARA CA 93101

Re: K102683
Trade/Device Name: The-Addition
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: December 2, 2010
Received: December 3, 2010

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5. *Indications for Use Statement*

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102683

Device Name: **The-Addition**

Indications for Use:

The-Addition provides padding for patient comfort and aids in the retention of coupling media in a defined position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use __X__ (Per 21 CFR 801.109)

Over-The-Counter Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102683